DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 2002

Endo Surgical Devices, Inc.
c/o Debbie Iampietro.
ORC Consulting
7 Tiffany Trail
Hopkinton, Massachusetts 01748

Re: K013680
Trade Name: Carbodissecting Endoscope
Regulation Number: 876.1500
Regulation Name: Laparoscope, General and Plastic Surgery
Regulatory Class: II
Product Code: GCJ
Dated: February 6, 2002
Received: February 11, 2002

Dear Ms. Iampietro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013680

Device Name: Carbodissecting Endoscope

Indications For Use:

To gently dissect planes of soft tissue using controlled bursts of CO_2 gas. The device may be used in both open and endoscopic procedures in which gentle, blunt dissection of soft tissue planes is desired.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013680

K013680

510K Summary of Safety and Effectiveness

1. Sponsor Name

Endo Surgical Devices, Inc.
4400 Rte 9 So., Suite 1000
Freehold, NJ 07728
Telephone: 732 409-5151

2. Device Name

Proprietary Name: Carbodissecting Endoscope
Common/Usual Name: Endoscope and Accessories
Classification Name: : Endoscope and Accessories

3. Identification of Predicate or Legally Marketed Device

- Sobel-Kaplitt-Sawyer Gas Spatula - Becton Dickenson and Company – Preamendments Device
- Cook Urological – CO_2 Pneumo-Dissector
- Guidant Corporation – Origin Medsystems - VasoView Balloon Dissection System

4. Device Description

The Carbodissecting Endoscope consists of two components:

The Spatula is a surgical tool used in combination with CO_2 and saline, and is designed to be used with the supplied Scope to provide accurate visual feedback during a carbodissection procedure. The tip allows the surgeon to slide between the tissue planes. The front of the tip is slightly curved and has multiple CO_2 outlets. The multiple CO_2 outlets are used to fan the gas out along the entire front of the tip to help peel apart the two layers, to aid in the separation of the tissue

The Scope is a flexible fiberscope intended for use with the Spatula.

5. Intended Use

To gently dissect planes of soft tissue using controlled bursts of CO_2 gas. The device may be used in both open and endoscopic procedures in which gentle, blunt dissection of soft tissue planes is desired.